OCT 31 2001

Proprietary to Horizon Medical Products, Inc.

510(k) Summary of Safety and Effectiveness
Super C™ Hemodialysis/Apheresis Chronic Catheter

Date Summary Was Prepared: June 15, 2001

Submitter's Information:
Horizon Medical Products, Inc.
One Horizon Way
Manchester, Georgia 31816

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Contact Person: Penny Northcutt, Director of Regulatory Affairs

Device Trade Name: Super C™ Hemodialysis/Apheresis Chronic Catheter

Device Common Name: Long Term Implanted Hemodialysis Catheter

Classification Name: Catheter, Hemodialysis, Implanted

Classification Panel: Gastroenterology

Legally Marketed Devices To Which Substantial Equivalence Is Claimed To:
The Super C™ Hemodialysis/Apheresis Chronic Catheter is substantially equivalent to

- Horizon Medical Products'13.5 French Chronic Dual Lumen Dialysis Catheter (Akcess Cath)
- Bard Vas Cath Opti-Flow 14.5 French Dual Lumen Catheter
- MedComp Ash Split 14 French, 28 cm Chronic Double Lumen Catheter.

Device Description: The Super C™ Hemodialysis/Apheresis Chronic Catheter is composed of a radiopaque polyurethane catheter shaft with two lumens (arterial and venous) in a Crescent (Circle "C") configuration. The lumens are distinguishable by color-coded clamps on clear silicone extensions.

The fixed retention cuff on the shaft provides an anchoring site for tissue ingrowth during long-term placement.

The Super C™ Hemodialysis/Apheresis Chronic Catheter offered in straight versions are available in 19 cm, 23 cm, and 28 cm cuff to tip insertion lengths. Additionally, the Super C™ Hemodialysis/Apheresis Chronic Catheter is available with a J-Cannula version in 19 cm and 23 cm cuff to tip insertion lengths.

Intended Use: The Super C™ Hemodialysis/Apheresis Chronic Catheter is indicated for use in attaining short and long term vascular access for hemodialysis, hemoperfusion or apheresis therapy via the jugular or subclavian vein. The catheter is intended for implantation dwell time of greater than 30 days.

Technological Characteristics: The technological characteristics of the Super C™ Hemodialysis/Apheresis Chronic Catheter, including material type, intended use, operating principle, number of lumens and performance characteristics are similar to the Bard's Vas-Cath Opti-Flow Dual Lumen Catheter and MedComp's Ash Split Catheter.

Performance Data: Performance testing was conducted data for Super C™ Hemodialysis/Apheresis Chronic Catheter and compared to the predicate devices identified in this 510(k). Test results demonstrated that the Super C™ Hemodialysis/Apheresis Chronic Catheter is substantially equivalent to these predicate devices commercially in distribution for the same intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2001

Ms. Patricia D. Jones
Regulatory Affairs Specialist
Horizon Medical Products, Inc.
One Horizon Way
MANCHESTER GA 31816

Re: K011916
Trade/Device Name: Super C™ Hemodialysis/Apheresis Chronic Catheter
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: 78 MSD
Dated: September 21, 2001
Received: September 24, 2001

Dear Ms. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration (21 CFR Part 807); listing (21 CFR Part 807), labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR §1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive, Abdominal,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K011916

PREMARKET NOTIFICATION

INDICATION FOR USE STATEMENT

510(k) Number: ~~**Unassigned**~~ K011916

Device Name: **Super C™ Hemodialysis/Apheresis Chronic Catheter**

Indication for Use:

The Super C™ Hemodialysis/Apheresis Chronic Catheter is indicated for use in attaining short and long term vascular access for hemodialysis, hemoperfusion or apheresis therapy via the jugular or subclavian vein. The catheter is intended for implantation dwell time of greater than 30 days.

_____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-the-Counter Use _____
(Per 21 CFR 801.109)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K011916